

Express Mail Number: EV 40699 2526 US

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| <b>TRANSMITTAL LETTER TO THE UNITED STATES<br/>DESIGNATED/ELECTED OFFICE (DO/EO/US)<br/>CONCERNING A FILING UNDER 35 U.S.C. 371</b>  |                           | <b>ATTORNEY'S DOCKET NUMBER</b><br><br><b>868_006</b>                          |
|  |                           | <b>U.S. APPLICATION NO. (If known, see 37 CFR 1.5)</b><br><br><b>10/530125</b> |
| INTERNATIONAL APPLICATION NO.  | INTERNATIONAL FILING DATE | PRIORITY DATE CLAIMED  |
| PCT/JP2003/013020  | October 10, 2003          | October 11, 2002   |
| TITLE OF INVENTION   |                           |  |
| GLP-1 DERIVATIVE AND PREPARATION THEREOF ABSORBABLE VIA MUCOUS MEMBRANE  |                           |  |
| APPLICANT(S) FOR DO/EO/US  |                           |  |
| Yuji HAYASHI, Mitsuhiro MAKINO, Toshiyuki KOUZAKI, Motohiro TAKEDA and Takahito JOMORI   |                           |  |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:  |                           |  |
| 1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a submission under 35 U.S.C. 371.<br>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a submission under 35 U.S.C. 371.<br>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.<br>4. <input type="checkbox"/> The US has been elected (Article 31).<br>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))<br>a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> has been communicated by the International Bureau.<br>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).<br>6. <input checked="" type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).<br>a. <input checked="" type="checkbox"/> is attached hereto.<br>b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4).<br>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))<br>a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau).<br>b. <input type="checkbox"/> have been communicated by the International Bureau.<br>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.<br>d. <input checked="" type="checkbox"/> have not been made and will not be made.<br>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).<br>9. <input type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).<br>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c))(5)).<br> |                           |  |
| <b>Items 11 to 20 below concern document(s) or information included:</b>   |                           |  |
| 11. <input checked="" type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.<br>12. <input type="checkbox"/> An Assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.<br>13. <input checked="" type="checkbox"/> A Preliminary Amendment.<br>14. <input checked="" type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.<br>15. <input type="checkbox"/> A Substitute Specification.<br>16. <input type="checkbox"/> A Power of Attorney and/or Change of Address Letter.<br>17. <input checked="" type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.<br>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).<br>19. <input type="checkbox"/> A second copy of the English language translation of the International Application under 35 U.S.C. 154(d)(4).<br>20. <input checked="" type="checkbox"/> Other items or information: International Publication (front page only)   |                           |  |
| Transmittal of Sequence Listing Under 37 C.F.R. §1.821 (2 pages), a Sequence Listing (on paper) and a Sequence Listing on Disk   |                           |  |

|   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
|---|-------------------------------|--|--|--------------|--|--------------|--|----------|-----------|------------|----------------------------|-----------|--------|------------|---|----------|--|------------|---|----------|--|--|----------------------------|-----------|-----------|--|
| U.S. APPLICATION NO. (If known, see 37 CFR 1.5)   | INTERNATIONAL APPLICATION NO. | ATTORNEY'S DOCKET NUMBER   |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>10/530125</b>  | PCT/JP2003/013020             | <b>868_006</b>   |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>The following fees are submitted:</p> <table border="1"> <tr> <td>21. <input checked="" type="checkbox"/> Basic National Fee .....</td> <td>\$300.00</td> <td>Calculations</td> <td>PTO Use Only</td> </tr> <tr> <td>22. <input checked="" type="checkbox"/> Examination Fee<br/>If International Preliminary Examination Report prepared by USPTO and<br/>all claims satisfy provisions of PCT Article 33(1)-(4) .....</td> <td>\$100.00</td> <td>\$ 300.00</td> <td></td> </tr> <tr> <td>All other situations .....</td> <td>\$ 200.00</td> <td>200.00</td> <td></td> </tr> <tr> <td>23. <input checked="" type="checkbox"/> Search Fee<br/>Search Fee has been paid on the International Application to USPTO as ISA .....</td> <td>\$100.00</td> <td></td> <td></td> </tr> <tr> <td>International Search Report prepared and provided to the Office .....</td> <td>\$400.00</td> <td></td> <td></td> </tr> <tr> <td>All other situations .....</td> <td>\$ 500.00</td> <td>\$ 400.00</td> <td></td> </tr> </table> |                               |  | 21. <input checked="" type="checkbox"/> Basic National Fee ..... | \$300.00     | Calculations   | PTO Use Only | 22. <input checked="" type="checkbox"/> Examination Fee<br>If International Preliminary Examination Report prepared by USPTO and<br>all claims satisfy provisions of PCT Article 33(1)-(4) ..... | \$100.00 | \$ 300.00 |            | All other situations ..... | \$ 200.00 | 200.00 |            | 23. <input checked="" type="checkbox"/> Search Fee<br>Search Fee has been paid on the International Application to USPTO as ISA ..... | \$100.00 |  |            | International Search Report prepared and provided to the Office ..... | \$400.00 |  |  | All other situations ..... | \$ 500.00 | \$ 400.00 |  |
| 21. <input checked="" type="checkbox"/> Basic National Fee .....  | \$300.00                      | Calculations   | PTO Use Only   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| 22. <input checked="" type="checkbox"/> Examination Fee<br>If International Preliminary Examination Report prepared by USPTO and<br>all claims satisfy provisions of PCT Article 33(1)-(4) .....  | \$100.00                      | \$ 300.00  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| All other situations .....  | \$ 200.00                     | 200.00   |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| 23. <input checked="" type="checkbox"/> Search Fee<br>Search Fee has been paid on the International Application to USPTO as ISA .....   | \$100.00                      |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| International Search Report prepared and provided to the Office .....   | \$400.00                      |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| All other situations .....  | \$ 500.00                     | \$ 400.00  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>\$ 900.00</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>[ ] Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250.00 for each additional 50 sheets of paper or fraction thereof.</p> <table border="1"> <tr> <td>Total Sheets</td> <td>Extra Sheets</td> <td>Number of each additional 50 sheets or fraction thereof (round up to a whole number)</td> <td>Rate</td> </tr> <tr> <td>36 - 100 =</td> <td>0/50 =</td> <td>0</td> <td>x \$250.00</td> </tr> </table>  |                               |  | Total Sheets   | Extra Sheets | Number of each additional 50 sheets or fraction thereof (round up to a whole number) | Rate         | 36 - 100 =   | 0/50 =   | 0         | x \$250.00 |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| Total Sheets  | Extra Sheets                  | Number of each additional 50 sheets or fraction thereof (round up to a whole number) | Rate   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| 36 - 100 =  | 0/50 =                        | 0  | x \$250.00   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>Surcharge of <b>\$130.00</b> for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).</p>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>130.00</b>   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <table border="1"> <tr> <td>CLAIMS</td> <td>NUMBER FILED</td> <td>NUMBER EXTRA</td> <td>RATE</td> </tr> <tr> <td>Total Claims</td> <td>17 -20 =</td> <td>0</td> <td>x \$50.00</td> </tr> <tr> <td>Independent Claims</td> <td>3 - 3 =</td> <td>0</td> <td>x \$200.00</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIM(S) (if applicable)</td> <td>+ \$360.00</td> </tr> </table>  |                               |  | CLAIMS   | NUMBER FILED | NUMBER EXTRA   | RATE         | Total Claims   | 17 -20 = | 0         | x \$50.00  | Independent Claims         | 3 - 3 =   | 0      | x \$200.00 | MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |          |  | + \$360.00 |   |          |  |  |                            |           |           |  |
| CLAIMS  | NUMBER FILED                  | NUMBER EXTRA   | RATE   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| Total Claims  | 17 -20 =                      | 0  | x \$50.00  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| Independent Claims  | 3 - 3 =                       | 0  | x \$200.00   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| MULTIPLE DEPENDENT CLAIM(S) (if applicable)   |                               |  | + \$360.00   |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>TOTAL OF ABOVE CALCULATIONS =</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>\$ 1,030.00</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>[ ] Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by <math>\frac{1}{2}</math>.</p>   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>SUBTOTAL =</b>   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>\$ 1,030.00</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>Processing fee of <b>\$130.00</b> for furnishing the English Translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</p>   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| +   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>TOTAL NATIONAL FEE =</b>   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>\$ 1,030.00</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). <b>\$40.00 per property</b></p>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| +   |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>TOTAL FEES ENCLOSED =</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <b>\$ 1,030.00</b>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <table border="1"> <tr> <td>Amount to be refunded:</td> <td>\$</td> </tr> <tr> <td>Amount to be charged:</td> <td>\$</td> </tr> </table>  |                               |  | Amount to be refunded:   | \$           | Amount to be charged:  | \$           |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| Amount to be refunded:  | \$                            |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| Amount to be charged:   | \$                            |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>a. <input checked="" type="checkbox"/> A check in the amount of \$1,030.00 to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. <u>50-1446</u> in the amount of \$ _____ to cover the above fees.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-1446</u>. A duplicate copy of this sheet is enclosed.</p>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.</p>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |
| <p>SEND ALL CORRESPONDENCE TO: Customer No. 025191</p> <p>Burr &amp; Brown<br/>P.O. Box 7068<br/>Syracuse, NY 13261-7068</p> <p>Telephone: (315) 233-8300<br/>Facsimile: (315) 233-8320</p> <p><i>Kevin C. Brown</i><br/>Kevin C. Brown<br/>Reg. No. 32,402</p> <p>Date: April 4, 2005</p>  |                               |  |  |              |  |              |  |          |           |            |                            |           |        |            |   |          |  |            |   |          |  |  |                            |           |           |  |

10/530125

Practitioner's Docket No.: 868\_006

PATENT

## IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

|  |   |   |
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| PCT/JP2003/013020<br>INTERNATIONAL APPLICATION NO. | October 10, 2003<br>INTERNATIONAL FILING DATE | October 11, 2002<br>PRIORITY DATE CLAIMED |
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**TITLE OF INVENTION**  
**GLP-1 DERIVATIVE AND PREPARATION THEREOF ABSORBABLE VIA MUCOUS MEMBRANE**

**APPLICANT(S) FOR DO/US**  
**Yuji HAYASHI, Mitsuhiro MAKINO, Toshiyuki KOUZAKI, Motohiro TAKEDA and Takahito JOMORI**

## EXPRESS MAIL CERTIFICATE

"Express Mail" label number: **EV 40699 2526 US**  
 Date of Deposit: **April 4, 2005**

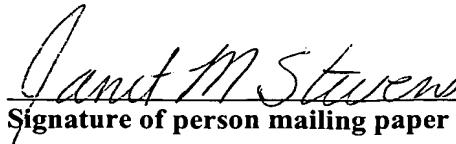
I hereby state that the following *attached* paper or fee

- A Transmittal Letter to the U.S. DO/EO/US Concerning a Filing Under 35 U.S.C. 371 (2 pages) (in duplicate)
- A Patent Application Bibliographic Data Sheet (4 pages)
- A copy of the International Application as filed (53 pages)
- A Translation of the International Application into English consisting of:
  - 32 pages of Specification (pages 1-32)
  - 2 pages of Claims (17 claims, 3 indep.) (pages 33-34)
  - 1 page Abstract (page 35)
- A Transmittal of Sequence Listing Under 37 C.F.R. §1.821 (2 pages), a Sequence Listing (on paper) (pages 1-9) and a Sequence Listing on Disk
- A Preliminary Amendment (pages 1-8)
- International Publication (front page only),
- An Information Disclosure Statement (2 pages), Form PTO-1449 (1 page), an International Search Report (5 pages) and three (3) references, and
- Our check in the amount of \$1,030.00 for:

is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10, on the date indicated above and is addressed to:

**Mail Stop PCT**  
**Attention: DO/US**  
**Commissioner for Patents**  
**P.O. Box 1450**  
**Alexandria, VA 22313-1450.**

Janet M. Stevens



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**Signature of person mailing paper or fee**